

(4) Not for use in horses intended for food.

[40 FR 13881, Mar. 27, 1975, as amended at 40 FR 48676, Oct. 17, 1975; 48 FR 31386, July 8, 1983; 52 FR 7833, Mar. 13, 1987; 58 FR 14314, Mar. 17, 1993; 59 FR 31140, June 17, 1994; 60 FR 45042, Aug. 30, 1995; 60 FR 48894, Sept. 21, 1995; 61 FR 17830, Apr. 23, 1996; 62 FR 611, Jan. 6, 1997; 62 FR 35077, June 30, 1997; 63 FR 6644, Feb. 10, 1998; 68 FR 59881, Oct. 20, 2003]

**§529.1044b Gentamicin sulfate solution.**

(a) *Specifications.* Each milliliter of solution contains gentamicin sulfate equivalent to 50 milligrams of gentamicin base.

(b) *Sponsor.* See Nos. 000061 and 051259 in §510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is recommended as an aid in the reduction or elimination of the following microorganisms from turkey-hatching eggs: *Arizona hinshawii* (paracolon), *Salmonella st. paul*, and *Mycoplasma meleagridis*.

(2) The drug is added to clean water to provide a dip solution with a gentamicin concentration of 250 to 1,000 parts per million. A concentration of 500 parts per million is recommended. Clean eggs should be held submerged in the gentamicin solution under a vacuum of about 27.5 to 38 centimeters of mercury for 5 minutes followed by additional soaking in gentamicin solution for approximately 10 minutes at atmospheric pressure. Eggs can also be treated by warming them for 3 to 6 hours at approximately 100 °F. then immediately submerging them in gentamicin solution maintained at about 40 °F., keeping the eggs submerged for 10 to 15 minutes.

(3) For use in the dipping treatment of turkey-hatching eggs only. Eggs which have been dipped in the drug shall not be used for food.

[40 FR 13881, Mar. 27, 1975, as amended at 52 FR 7833, Mar. 13, 1987; 62 FR 22889, Apr. 28, 1997]

**§529.1115 Halothane.**

(a) *Specifications.* The drug is a colorless, odorless, nonflammable, nonexplosive, heavy liquid containing 0.01 percent thymol as a preservative.

(b) *Sponsor.* See 000856 and 012164 in §510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Two to 5 percent of inhaled atmosphere for induction of anesthesia; 0.5 to 2 percent for maintenance of anesthesia.<sup>1</sup>

(2) *Indications for use.* For nonfood animals for the induction and maintenance of anesthesia.<sup>1</sup>

(3) *Limitations.* Administered by inhalation. May be administered with either oxygen or a mixture of oxygen and nitrous oxide. Place drug vaporizer between the gas supply and breathing bag to prevent overdosage. Not recommended for obstetrical anesthesia except when uterine relaxation is required. Do not use in pregnant animals; information on possible adverse effects on fetal development is not available. Operating rooms should have adequate ventilation to prevent accumulation of anesthetic gases. Not for use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.<sup>1</sup>

[46 FR 27915, May 22, 1981, as amended at 62 FR 29014, May 29, 1997]

**§529.1186 Isoflurane.**

(a) *Specifications.* The drug is a clear, colorless, stable liquid containing no additives or chemical stabilizers. It is nonflammable and nonexplosive.

(b) *Sponsors.* See Nos. 000074, 000209, 010019, 012164, 059258, and 060307 in §510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Horses:* For induction of surgical anesthesia: 3 to 5 percent isoflurane (with oxygen) for 5 to 10 minutes. For maintenance of surgical anesthesia: 1.5 to 1.8 percent isoflurane (with oxygen).

(ii) *Dogs:* For induction of surgical anesthesia: 2 to 2.5 percent isoflurane (with oxygen) for 5 to 10 minutes. For maintenance of surgical anesthesia: 1.5 to 1.8 percent isoflurane (with oxygen).

(2) *Indications for use.* For induction and maintenance of general anesthesia in horses and dogs.

<sup>1</sup>These conditions have been reviewed by FDA and found effective. NADA's for similar products for these conditions of use need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.

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(3) *Limitations.* Administer by inhalation; not for use in horses or dogs sensitive to halogenated agents; increasing depth of anesthesia may increase hypotension and respiratory depression; use less than usual amounts of nondepolarizing relaxants; use with vaporizers producing predictable percentage concentrations; not for use in horses intended for food; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[51 FR 594, Jan. 7, 1986, as amended at 54 FR 23472, June 1, 1989; 58 FR 17346, Apr. 2, 1993; 59 FR 44315, Aug. 29, 1994; 60 FR 40456, Aug. 9, 1995; 63 FR 8122, Feb. 18, 1998; 63 FR 24106, May 1, 1998; 66 FR 17510, Apr. 2, 2001]

## § 529.1526 Nifurpirinol capsules.

(a) *Specifications.* Each capsule contains 3.8 or 7.6 milligrams of nifurpirinol.

(b) *Sponsor.* See No. 000074 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in treating aquarium fish for the control of columnaris disease caused by *Chondrococcus columnaris* susceptible to nifurpirinol.

(2) Use one 3.8 milligram nifurpirinol capsule for each 10 gallons of aquarium water. Empty the contents of the capsule directly into the water and stir briefly. Treat for at least 1 hour. If activated charcoal or carbon filtration is being used, disconnect during treatment, but maintain adequate aeration. Resume water filtration after 1 hour treatment. Usually a single treatment is sufficient. For aquariums with charcoal filters, nifurpirinol can be used once each 24 hours up to 3 consecutive days, discontinuing filtration during treatment. If aquarium does not have charcoal filter, do not retreat within 5 days.

(3) Do not use in salt water aquariums.

(4) Do not use while egg bearers or live bearers are reproducing.

[40 FR 60052, Dec. 31, 1975, as amended at 47 FR 20758, May 14, 1982; 56 FR 43699, Sept. 4, 1991]

## § 529.1660 Oxytetracycline.

(a) *Specifications*—(1) Each gram of powder contains 366 milligrams (mg) oxytetracycline hydrochloride.

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(2) Each gram of powder contains 753 mg oxytetracycline hydrochloride.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use of products described in paragraph (a) of this section as in paragraph (d) of this section.

(1) No. 046573 for use of product described in paragraph (a)(1) of this section.

(2) No. 059130 for use of product described in paragraph (a)(2) of this section.

(c) *Related tolerances.* See § 556.500 of this chapter.

(d) *Conditions of use in finfish*—(1) *Amount.* Immerse fish in a solution containing 200 to 700 mg oxytetracycline hydrochloride (buffered) per liter of water for 2 to 6 hours.

(2) *Indications for use.* For skeletal marking of finfish fry and fingerlings.

[69 FR 6557, Feb. 11, 2004, as amended at 69 FR 61999, Oct. 22, 2004]

## § 529.1940 Progesterone intravaginal inserts.

(a) *Specifications.* Each insert contains 1.38 grams of progesterone in molded silicone over a nylon spine.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.540(a) of this chapter.

(d) *Special considerations.* (1) Product labeling shall bear the following warnings: “Avoid contact with skin by wearing latex gloves when handling inserts. Store removed inserts in a plastic bag or other sealable container until they can be disposed of in accordance with applicable local, State, and Federal regulations.”

(2) This product is approved with the concurrent use of dinoprost solution on day 6 of the 7-day administration period when used for indications listed in paragraph (e)(2)(i) of this section. See § 522.690(c) of this chapter.

(e) *Conditions of use*—(1) *Amount.* Administer one intravaginal insert per animal for 7 days. When used for indications listed in paragraph (e)(2)(i) of this section, administer 25 milligrams (mg) dinoprost (5 milliliters (mL) of 5 mg/mL solution as in § 522.690(a) of this chapter) as a single intramuscular injection one day prior to insert removal.